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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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OBLON, SPIVAK, MCCLELLAND, MAIER & NEUSTADT, P.C.
1940 DUKE STREET
ALEXANDRIA, VA 22314

EXAMINER

WILLSE, DAVID H

ART UNIT PAPER NUMBER

3738

40

DATE MAILED: 08/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/121,300

Applicant(s)

KANIA ET AL.

Examiner

Dave Willse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 75-78,80,83-96 and 98-121 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 75-78,80,83-96 and 98-121 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

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Claims 75-78, 80, 83-96, and 98-105 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The term “nonporous” or “non-porosity” is nowhere to be found in the original disclosure, and the Applicant has not provided any evidence that such a feature would have been gleaned from the examples at pages 29-32 or elsewhere in the specification by the ordinary practitioner. In fact, many of the originally disclosed embodiments involve *foamed* cushioning materials, as seen from the discussion on page 14, lines 6-19. Because of the procedure outlined in M.P.E.P. 2163.06 for interpreting the claims, it is noted that other art may be applicable under 35 U.S.C. 102 or 35 U.S.C. 103(a) once the aforementioned problem under 35 U.S.C. 112, first paragraph, is corrected.

Claims 85-87 and 98-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 85 and others, it is unclear whether the same (as in claim 75) or additional “polymeric cushioning material” is being claimed. Claims 98, 100, and 101 depend from a canceled claim.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 106 and 114 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Norman, GB 2 213 380 A. Regarding claim 106, the ePTFE membrane **10** can be pre-laminated (and hence coated seamlessly and directly) to a knitted nylon (page 4, lines 14-15). Regarding claim 114, because of the flexibility of the materials, the device is *capable* of being inverted and rolled onto the amputation stump, whether or not such was the intent.

Claims 108, 109, 116, and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Norman, GB 2 213 380 A. Regarding claims 108, 109, 116, and 117, docking means molded into the liner was common in the art at the time of the present invention and would have been obvious in order to better secure the liner to the artificial limb **14**.

Claims 75, 78, 80, 85, 106, 107, 114, and 115 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Lerman, US 4,635,626. Since the alternative neoprene rubber is *not* porous to air and water (column 5, lines 19-24), it is deemed to be "nonporous" (instant claim 75, line 4). Regarding claim 106, the polymeric cushioning material comprises the adhesive layer itself and optionally the base layer **52** in combination. Regarding claim 114, because of the flexible, stretchable nature of the materials disclosed by Lerman, the stump sock is clearly capable of being inverted and rolled onto the amputation stump.

Claims 83, 84, 86-91, 108, 109, 116, and 117 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lerman, US 4,635,626. Regarding claim 83 and others, the docking

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means as claimed would have been obvious for reasons cited above. Regarding claims 88 and 89, biocides and vitamins, well known in the art, would have been obvious in order to help prevent or treat infections on the residuum. Regarding claims 90 and 91, liners having sensing or detecting means for transmitting a signal from the residual limb to a prosthetic device were likewise well known in the art and would have been obvious in order to provide the amputee with greater control of the prosthesis through myoelectric signals, muscular movements, and the like.

Claims 75-78, 80, 83-96, and 98-121 are rejected under 35 U.S.C. 103(a) as being unpatentable over LPRI, SU 1739990 A1. Regarding claim 75 and others, LPRI discloses all of the elements except that the cushions 2 and 3 are of a foamed or porous polymeric cushioning material. However, various nonporous materials were common in the art for such a function at the time of the instant invention, and since the Applicant's original disclosure is silent as to any supposed criticality of nonporous materials over porous materials (*In re Kuhle*, 188 USPQ 9), nonporous cushions 2 and 3 would have been an obvious alternative choice of materials in order to incorporate advantageous characteristics (as taught in the art) of materials that happen to be nonporous with the benefits of the LPRI invention pertaining to reduction of trauma to the skin covering bony prominences (page 4, lines 15-16, of the English translation). It is not clear from the English translation of LPRI whether the elastomer impregnation of the fabric layers 1 results in a minute elastomeric coating on the outer surface of the liner. However, many, if not all, of the Applicant's own embodiments make use of impregnation (e.g., page 8, lines 9-10; page 22, lines 18-20; page 30, line 16), and some embodiments explicitly include outer coatings (e.g., page 1, lines 16-20; page 16, last four lines; page 26, lines 18-19; original claim 9). Partial or no


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impregnation in the LPRI invention would thus have been an obvious step backward in order to simplify the manufacturing process, particularly in the absence of any teaching in the Applicant's original disclosure to avoid thorough impregnation of the fabric. The further limitations of claim 83 and others would have been obvious for reasons cited above.

The Applicant's remarks have been reviewed. Regarding the Norman reference, the examiner refers to page 4, lines 14-16, of GB 2 213 380 A (not to page 4, lines 14-16, of the Applicant's specification); the term "seamless" or "seamlessly" does not even appear in the Applicant's original disclosure. Other issues are adequately addressed in the grounds of rejection presented above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse, who is available Monday through Thursday and whose telephone number is (703) 308-2903. The supervisor, Corrine McDermott, can be reached at (703) 308-2111. The receptionist's phone number is (703) 308-0858, and the main FAX numbers are (703) 305-3591, 3590.

dhw: D. Willse
August 18, 2003


DAVE WILLSE
PRIMARY EXAMINER
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